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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,378	08/27/2001	Gust H. Bardy	032580.0017.UTL	2603
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CROMPTON SEAGER AND TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
EXAMINER MULLEN, KRISTEN DROESCH				
ART UNIT		PAPER NUMBER		
3762				

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/940,378	Applicant(s) BARDY ET AL. <i>CM</i>	
	Examiner Kristen Mullen	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/30/04 (Response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105,106,108,110,113-119,121 and 122 is/are rejected.
- 7) ☒ Claim(s) 107,109,111,112,120 and 123 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 105, 108, 116, 117, 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Duffin Jr. (5,243,978).

Regarding claims 105, 117, and 121, Duffin Jr. shows a method of treating an abnormal cardiac rhythm by pacing the patient's heartbeat by comprising providing a pair of stimulus electrodes (12, 15) disposed internal to a patient and exclusive of the patient's heart; providing an implantable stimulus device (25) at a subcutaneous location; sensing an event in the patient's cardiac rhythm; transferring energy from an energy source (battery) to an energy storage system (capacitor); and discharging energy from the energy storage system using the electrode pair and determining whether the patient has an abnormally slow heartbeat, and wherein the step of sensing an event in the patient's sinus rhythm provides information for determining whether the patient has an abnormally slow heartbeat (Col. 4, lines 20-25; Col. 5, lines 25-65; Figs. 1-2).

Exclusive to the patient's heart has been interpreted as not entering the heart.

With respect to claim 108, Duffin Jr. shows providing an implantable stimulus device (5) into the patient which houses the energy source and the energy storage system and which is coupled to a lead system including at least one electrode of the electrode pair (12, 15).

With respect to claims 116, and 122, Duffin Jr. shows the step of providing a pair of electrodes includes providing a pair of electrodes outside a patient's vasculature (Figs. 1-2).

Regarding claim 118, Duffin Jr. shows the step of determining whether the patient has an abnormally slow heartbeat comprises using two sensing electrodes both disposed exclusive of the patient's heart (12, 15)

3. Claims 113 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams (5,441,518). Adams shows method including providing a pair of electrodes (11, 14) disposed internal to a patient and exclusive of the patient's heart, transferring energy from an energy source to an energy storage system, and discharging energy from the energy storage system using the electrode pair in combination with at least one of the pair of electrodes (11) being located on a housing for the stimulus device.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duffin Jr. (5,243,978) in view of Bardy (5,292,338). Duffin Jr. is as explained before. Duffin Jr. fails to specifically point out that the pacemaker is implanted subcutaneously between the third rib and the twelfth rib of the patient. Attention is directed to Bardy, which teaches a known pacemaker/defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same

Art Unit: 3762

location or level as the third rib (23) in the pectoral region. Thus, if the known pacemaker/defibrillator Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Duffin Jr. subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

6. Claim 119 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duffin Jr. (5,243,978) in view of Bennett et al. (5,331,966). Duffin Jr is as explained before. Duffin Jr. fails to show the step of determining whether the patient has an abnormally slow heartbeat includes using two sensing electrodes disposed exclusive of the patient's heart where at least one of the sensing electrodes is not one of the stimulus electrodes, attention is directed to Bennett et al. which teaches an implantable stimulus device with electrodes located on the device housing. Bennett teaches that providing multiple sensing electrodes (A, B, C) on the device housing provides a leadless orientation insensitive means for receiving electrical signals from the heart (Abs). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device housing of Duffin Jr. with the device housing incorporating sensing electrodes as Bennett et al teaches in order to provide a leadless orientation insensitive means for receiving electrical signals from the heart.

7. Claims 114-115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,441,518) in view of Bennett et al. (5,331,966). Adams is as explained before. Although Adams fails to show the step of sensing a cardiac event includes sensing a potential between electrodes disposed internal to the patient and exclusive of the patient's heart, attention is

Art Unit: 3762

directed to Bennett et al. which teaches an implantable stimulus device with electrodes located on the device housing. Bennett teaches that providing multiple sensing electrodes (A, B, C) on the device housing provides a leadless orientation insensitive means for receiving electrical signals from the heart (Abs). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device housing of Adams with the device housing incorporating sensing electrodes as Bennett et al teaches in order to provide a leadless orientation insensitive means for receiving electrical signals from the heart.

Regarding claim 115, Adams further shows one of the sensing electrodes (housing electrode) is also one of the pair of electrodes used to discharge energy to the patient.

Response to Arguments

8. Applicant's arguments with respect to claim 105-106, 108, 110, 113-119, and 121-122 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

9. Claims 107, 109, 111-112, 120, and 123 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Regarding claim 107, the prior art of record fails to teach or suggest a method of treating an abnormal cardiac rhythm by pacing the patient's heartbeat by comprising providing a pair of stimulus electrodes disposed internal to a patient and exclusive of the patient's heart; providing an implantable stimulus device at a subcutaneous location; sensing an event in the patient's cardiac rhythm; transferring energy from an energy source to an energy storage system; and discharging energy from the energy storage system using the electrode pair and determining

Art Unit: 3762

whether the patient has an abnormally slow heartbeat, and wherein the step of sensing an event in the patient's sinus rhythm provides information for determining whether the patient has an abnormally slow heartbeat, in combination with the pair of electrodes including a first electrode disposed on a stimulus device housing the energy source and storage system.

With respect to claim 120, the prior art of record fails to teach or suggest a method of pacing a patient through a bradycardia event including providing a pair of electrodes exclusive of the patient's heart; providing an implantable stimulus device at a subcutaneous location which is connected to a lead system including at least one electrode of the electrode pair, determining whether the patient has an abnormally slow heartbeat by sensing events in the patient's sinus rhythm; transferring energy from an energy source to an energy storage system, discharging energy from the energy storage system using the electrode pair in combination with one of the stimulus electrodes disposed on the implantable stimulus device.

Regarding claim 123, the prior art of record fails to teach or suggest a method of treating bradycardia comprising providing electrical pacing stimulus between two implanted electrodes disposed exclusive of the heart; in combination with one of the electrodes disposed on the implantable stimulus device canister.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Muller

kdm

Angela D. Sykes

ANGELA D. SYKES
SUPERVISOR, PATENT EXAMINER
TECHNOLOGY CENTER 3700